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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,091	12/04/2001	Jeong Gun Lee	041501-5485	8023

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EXAMINER

FORMAN, BETTY J

ART UNIT PAPER NUMBER

1634

DATE MAILED: 09/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/000,091	Applicant(s) LEE ET AL.	
	Examiner BJ Forman	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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FINAL ACTION

1. This action is in response to papers filed 15 July 2003 in which claims 1, 2, 4, 7 and 8 were amended and claims 10-20 were canceled. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 15 April 2003 under 35 U.S.C. 112, second paragraph are withdrawn in view of the amendments. The previous rejections under 35 U.S.C. 102, 35 U.S.C. 103 and obviousness-type double patenting are maintained. All of the arguments have been thoroughly reviewed and are discussed below.

Claims 1-9 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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3. Claims 1-2 and 5-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Hashimoto et al (U.S. Patent No. 5,776,672, issued 7 July 1998).

Regarding Claim 1, Hashimoto et al disclose a method for detecting DNA comprising: immobilizing a probe DNA on a chip, placing a target DNA on the chip to hybridize the target and probe DNA, intercalating an intercalator to the hybridized DNA, introducing an electrochemiluminescent reaction fluid into the chip, applying a preset voltage to cause a reaction between the intercalator and reaction fluid, and detecting and analyzing light from the reaction (Abstract; Column 4, lines 5-54; Examples 7-11, Columns 17-20; and Claims 1-9).

Regarding Claim 2, Hashimoto et al disclose the method wherein immobilizing the probe DNA includes the steps of washing an electrode, dipping the electrode in a mixed solution containing the probe DNA and washing a second time to immobilize the DNA (Column 8, line 36-Column 10, line 15 and Example 24, Column 39, lines 5-30).

Regarding Claim 5, Hashimoto et al disclose the method wherein the intercalator is selected from daunorubicin, nogalamycin, doxorubicin, and DAPI(4',6-diamidino-2-phenylindole), or, one selected from a material obtained by bonding proline, oxalic acid, or TPA (tripropylamine) with Hoechst 33258, quinacrine, or acridity orange(Column 4, lines 5-54).

Regarding Claim 6, Hashimoto et al disclose the method wherein the electrochemilucet reaction fluid is one selected from Tris(2,2'-bipyridyl)ruthenium(II)(Ru(bpy)₃²⁺), Tris(2,2'-bipyridyl)osmium(II)(Os(bpy)₃²⁺), and Tris (1,10-phenanthroline ruthenium (II) Ru(phen)₃²⁺ (Column 4, lines 5-54).

Regarding Claim 7, Hashimoto et al disclose the method wherein step (b) includes placing the target DNA on the chip, applying a first voltage to hybridize the probe and target, and applying a second charge for removing not hybridized DNA (Column 13, lines 21-30).

Regarding Claim 8, Hashimoto et al disclose the method wherein step (c) further includes washing the intercalators not intercalated to the hybridized DNA with a buffer solution (Column 12, lines 37-42).

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Regarding Claim 9, Hashimoto et al disclose the method wherein the preset voltage in step (e) is 0.5-1.20 V (Column 13, lines 13-20).

Response to Arguments

4. Applicant argues that Hashimoto et al do not teach or suggest immobilizing a DNA probe on a "chip" as instantly claimed. The argument has been considered but is not found persuasive because the courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111).

The instant specification broadly defines a DNA chip at paragraphs 5-6 as cited below:

"A DNA chip is developed, in which a two dimensional array of nucleic acids disposed onto solid substrate at known positions. The DNA chip permits search of genes from a few hundreds at the smallest, and to more than 400,000, quickly. The DNA chip, having an array of high concentration DNA fragments with a great variety of base sequences on a small substrate surface, is used for obtaining information of DNA in an unknown sample by hybridization with an immobilized DNA and a complementary DNA in the unknown sample."

Hashimoto et al teach a "base plate" comprising immobilized nucleic acid probes at known positions wherein the number of positions having the immobilized probes is not restricted (Column 26, line 61-Column 27, line 22 and Example 31). As such, the base plate of Hashimoto et al as encompassed by the instantly claimed chip as broadly defined by the specification. However, it is noted that limitations from the specification cannot be read into the claims (See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993)), the base plate of Hashimoto et al meets the broad definition of chip as recited in the specification.

5. Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee et al (U.S. Patent No. 6,342,359, filed 29 September 2000).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding Claim 1, Lee et al disclose a method for detecting DNA comprising: immobilizing a probe DNA on a chip, placing a target DNA on the chip to hybridize the target and probe DNA, intercalating an intercalator to the hybridized DNA, introducing an electrochemiluminescent reaction fluid into the chip, applying a preset voltage to cause a reaction between the intercalator and reaction fluid, and detecting and analyzing light from the reaction (Column 6, line 30-Column 8, line 67).

Regarding Claim 2, Lee et al disclose the method wherein immobilizing the probe DNA includes the steps of washing an electrode, dipping the electrode in a mixed solution containing the probe DNA and washing a second time to immobilize the DNA (Column 6, line 30-Column 7, line 35).

Regarding Claim 3, Lee et al disclose the method wherein step (a) includes washing an electrode the first time, dipping the electrode in a mixed solution containing the probe DNA and

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washing the electrode the second time thereby immobilizing the DNA (Column 6, line 30-Column 7, line35).

Regarding Claim 4, Lee et al disclose the method wherein the first washing includes the steps of dipping the electrode in piranha solution and water, the mixed solution containing probe DNA and w-hydroxy-undecanethiol 3 or 3-mercaptopropionic acid dissolved in ethanol/octane and the second washing includes washing in ethanol and water 6, line 30-Column 7, line35).

Regarding Claim 5, Lee et al disclose the method wherein the intercalator is selected from daunorubicin, nogalamycin, doxorubicin, and DAPI(4',6-diamidino-2-phenylindole), or, one selected from a material obtained by bonding proline, oxalic acid, or TPA (tripropylamine) with Hoechst 33258, quinacrine, or acridity orange (Column 4, lines 45-67).

Regarding Claim 6, Lee et al disclose the method wherein the electrochemiluent reaction fluid is one selected from Tris(2,2'-bipyridyl)ruthenium(II)(Ru(bpy)₃²⁺), Tris(2,2'-bipyridyl)osmium(II)(Os(bpy)₃²⁺), and Tris (1,10-phenanthroline ruthenium (II) Ru(phen)₃²⁺ (Column 4, lines 45-67).

Regarding Claim 7, Lee et al disclose the method wherein step (b) includes placing the target DNA on the chip, applying a first voltage to hybridize the probe and target, and applying a second charge for removing not hybridized DNA (Column 8, line 62-Column 9, line 15).

Regarding Claim 8, Lee et al disclose the method wherein step (c) further includes washing the intercalators not intercalated to the hybridized DNA with a buffer solution (Column 8, lines 54-61).

Regarding Claim 9, Lee et al disclose the method wherein the preset voltage in step (e) is 0.5-1.20 V (Column 8, lines 62-67).

Response to Arguments

6. Applicant argues that Lee et al do not teach introduction of an electrochemiluminescent reaction "fluid" to the chip and therefore cannot anticipate the instant

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claims. The argument has been considered but is not found persuasive because Claim 6 defines the reaction "fluid" as being selected from Tris(2,2'-bipyridyl)ruthenium(II)(Ru(bpy)₃²⁺), Tris(2,2'-bipyridyl)osmium(II)(Os(bpy)₃²⁺), and Tris(1,10-phenanthroline)ruthenium(II) Ru(phen)₃²⁺. Lee et al specifically teach the claimed reaction fluid (Column 4, lines 45-67 and Column 6, lines 10-24).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hashimoto et al (U.S. Patent No. 5,776,672, issued 7 July 1998) in view of Blackburn et al (U.S. Patent No. 6,264,825, filed 23 June 1999).

Regarding Claim 4, Hashimoto et al disclose a method for detecting DNA comprising: immobilizing a probe DNA on a chip, placing a target DNA on the chip to hybridize the target and probe DNA, intercalating an intercalator to the hybridized DNA, introducing an electrochemiluminescent reaction fluid into the chip, applying a preset voltage to cause a reaction between the intercalator and reaction fluid, and detecting and analyzing light from the

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reaction (Abstract; Column 4, lines 5-54; Examples 7-11, Columns 17-20; and Claims 1-9) wherein the electrode is formed of gold (Column 8, lines 44-54) and the probe DNA has a thiol (i.e. mercapto) functional group at a 5' phosphate position (Column 8, line 60-Column 9, line 32) but they are silent regarding the composition of the chip. However, methods for detecting DNA utilizing silicon chips comprising gold electrodes were well known in the art at the time the claimed invention was made as taught by Blackburn et al (Example 1-2: Column 89, line 5-Column 90) wherein the application of gold electrodes onto the chip provides a pattern of electrodes for conducting multiple detection assays simultaneously (Column 2, line 60-Column 3, line 15). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the well known silicon chip substrate of Blackburn et al to the substrate of Hashimoto et al and to apply the gold electrodes of Hashimoto onto the silicon chip to thereby provide a pattern on electrodes on the chip for the obvious benefits of conducting multiple detection assays simultaneously as taught by Blackburn et al (Column 2, line 60-Column 3, line 15 and Examples 1-2).

Response to Arguments

9. Applicant relies on the arguments discussed above regarding Hashimoto et al. Applicant further states that Blackburn et al do not cure the efficiencies of Hashimoto et al. The arguments have been considered but are not found persuasive as discussed above.

Applicant argues that the teaching of Hashimoto et al and Blackburn et al are directed to unrelated process and therefore, there would have been no motivation to combine their teachings. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir.

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1992). In this case, the processes of both Hashimoto et al (Abstract) and Blackburn et al (Abstract) are drawn to target binding and target detection utilizing electrodes. Furthermore, Blackburn et al provide a motivation to utilize gold electrodes i.e. the application of gold electrodes onto the chip provides a pattern of electrodes for conducting multiple detection assays simultaneously (Column 2, line 60-Column 3, line 15). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the well known silicon chip substrate of Blackburn et al to the substrate of Hashimoto et al and to apply the gold electrodes of Hashimoto onto the silicon chip to thereby provide a pattern on electrodes on the chip for the obvious benefits of conducting multiple detection assays simultaneously as taught by Blackburn et al (Column 2, line 60-Column 3, line 15 and Examples 1-2).

Double Patenting

10.. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13 and 15 of U.S. Patent No. 6,342,359. Although the conflicting claims are not identical, they are not patentably distinct from each other

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because both sets of claims are drawn to similar methods for detecting DNA and differ only in the arrangement of limitations within the claim sets. For example, Claim 13 of '359 is drawn to a method utilizing their device as claimed in Claim 1 which comprises probe DNA immobilized on a chip and the method recites the steps of oxidizing bipyridyl complexes or derivative thereof. Similarly, instant Claim 1 is drawn to a method which recites the method step of immobilizing probe DNA on a chip and recites the method step of introducing an electrochemicaluminescent reaction fluid which depend claim 6 defines as bipyridyl complexes and derivatives. As such, the '359 claims and instant claims are drawn to very similar methods encompassing the same limitations and therefore the claim sets are not patentably distinct.

Response to Arguments

12. Applicant relies on the arguments discussed above regarding Lee et al. The arguments have been considered but are not found persuasive for the reasons stated above.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
September 9, 2003